K042368

OCT 4 - 2004

510(k) Summary

In accordance with the requirements of 21 CFR 807.92

27 August 2004

1. **Contact person**
Lynn Harmer
Philips Medical Systems
22100 Bothell Everett Highway
Bothell, Washington 98021-8431
Phone: (425) 487-7312
Fax: (425) 487-8666

2. **Device name and classification**
Trade name: *Practix Convenio*
Classification name: *Mobile x-ray system*
Classification panel: *Radiology devices*
Regulatory status: *Class II*
Device classification reg. nr.: *21CFR 892.1720*

3. **Predicate device**
Trade name: *RT-125 ROUGH TERRAIN MOBILE X-RAY UNIT (also known as PMX 2000)*
Manufacturer: *Lorad*
510(k) Number: *K 894643*

4. **Description**
The *Practix Convenio* is a motor driven battery supplied mobile x-ray unit to be operated indoors only. The system contains: Battery cluster including battery charger, two passive and two motor driven wheels, 20 kHz converter x-ray generator excluding the high voltage unit, 360° turn able column and a telescope arm to carry x-ray unit, x-ray tank (x-ray tube housing assembly and high voltage unit), collimator (beam limiting device) and a drawer to carry x-ray film cassettes and an anti scatter grid. The following components are optional: Removable pre filter, dose area product measurement, automatic exposure control and an infrared remote control.

5. **Intended Use**
The *Practix Convenio* is a mains independent motor driven mobile x-ray system, to x-ray body parts of patients to create images for medical diagnostic purposes. The *Practix Convenio* is intended to x-ray in rooms for medical use.

6. **Comparison to predicate device**
The Practix Convenio does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the Practix Convenio to be substantially equivalent with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2004

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems North America
22100 Bothell Evert Highway
BOTHELL WA 98021-8431

Re: K042368
Trade/Device Name: Practix Convenio
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: 90 IZL
Dated: August 27, 2004
Received: August 31, 2004

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042368

Device Name: Practix Convenio

Indications For Use:

The *Practix Convenio* is a mains independent motor driven *mobile x-ray system*, to x-ray body parts of patients to create images for medical diagnostic purposes. The *Practix Convenio* is intended to x-ray in rooms for medical use.

Prescription Use __X__ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepmann

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042368